

Message

From: danielle.laroche@us.nufarm.com [danielle.laroche@us.nufarm.com]
Sent: 11/16/2016 7:35:18 PM
To: Johnson, Hope [Johnson.Hope@epa.gov]
Subject: Calcium Oxytetracycline / Mycoshield_Tolerance Petition

Hope,

A tolerance petition and application for the registration of Calcium Oxytetracycline / Mycoshield on citrus were submitted in September. A protocol for the resistance monitoring study that is required for antibiotics was included for the Agency's review. Can you please confirm or clarify the process for the review of the protocol and the timing for the conduct of the study? The following is my understanding based on information provided by Shaunta Hill when I contacted her during the preparation of the petition but I would appreciate your comments:

-the protocol should be submitted as part of the supporting information for the tolerance petition and application for registration of Mycoshield on citrus.

-Nufarm needs to wait for the Agency review of the protocol before initiating the resistance monitoring study

-the EPA will review the protocol at the same time with the supporting data included in the tolerance petition/application. A review of the protocol will be provided at the time a decision is made.

-if all supporting data are found to be acceptable, EPA would grant a conditional registration and would require the conduct of the resistance monitoring study according to the protocol (with any changes required by EPA). The timeline for the submission of the data will be specified at that time.

Any information you can provide to help us comply with the requirement for the resistance monitoring study would be greatly appreciated. Feel free to call me at (919) 379-2530 - I will be in the office all afternoon and tomorrow (except from 2 to 3).

Many thanks.

Danielle

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